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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/618,235    07/18/00    RUBINGH

D    7670

027748    HM12/1002  
THE PROCTER & GAMBLE COMPANY  
PATENT DIVISION  
MIAMI VALLEY LABORATORIES  
P.O. BOX 538707  
CINCINNATI OH 45253-8707

EXAMINER
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MOORE, W	
ART UNIT	PAPER NUMBER

1652

DATE MAILED:

10/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/618,235

Applicant(s)

RUBINGH ET AL.

Examiner

William W. Moore

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Information Disclosure Statement*

Applicant's four Information Disclosure Statements, Papers Nos. 2, 4, 5 and 7 filed, respectively, December 4, 2000, and January 17, June 4, and September 14, 2001, are hereby acknowledged. Executed copies of their accompanying PTO Forms 1449 will be provided for Applicant after the documents supplied therewith have been considered and a first communication on the merits prepared.

### *Election/Restrictions*

Restriction to one of the following patentably distinct species of inventions is required under 35 U.S.C. §121. While the claim structure does not, even in claims 3 and 4, acknowledge the need for substitutions at the great majority of positions recited in claims 1 and 12, and nowhere acknowledges the range of substituents that may be employed for covalent attachment, substituents for which the application provides an adequate written description, cysteine and lysine, are the basis for calculation of the following species:

Claims 1-21 are generic to a plurality of disclosed patentably distinct species comprising 178 species of singly-substituted and conjugated subtilisins and about 10,056 doubly-substituted and conjugated subtilisins where no doubly-substituted and conjugated subtilisins have both substitutions in a common epitope region. Many, many, more species are represented in subtilisins wherein double substitutions for conjugation reside in one of the regions described by clauses (a), (b) and (c) of claim 1, and triply-substituted and conjugated subtilisins, fourfold-substituted and conjugated subtilisins and higher order substitutions and conjugations of subtilisins constitute a galaxy of species.

Not restricted by this requirement are the nine further subspecies of potential arrays of conjugates at each substituted and conjugated position. Neither are the potential species of wild-type, unsubstituted, subtilisins that might become conjugated with a linking moiety restricted herein.

Applicant is required under 35 U.S.C. §121 to elect a single disclosed species, identifying the number and location of position(s) wherein (a) substitution(s) are made for conjugation is made, even though this requirement is traversed. If Applicant believes that examination of a reasonable number of additional species might be conducted with examination of an elected species, Applicant should indicate how the relationship of any further species to the elected species could permit a reasonable search and examination.

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other invention.

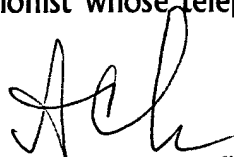
A telephone call was made to Ms. Dara M. Kendall on September 28, 2001, to request an oral election to the above restriction requirement, but did not result in an election being made. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 703.308.0583. The examiner can normally be reached from 8:00AM-6:30PM EST on Mondays, Wednesdays, and Fridays and from 11:30AM-6:00PM EST on Tuesdays and Thursdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached at 703.308.3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703.308.4242 for regular communications and 703.308.0294 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0196.

William W. Moore  
September 28, 2001

  
PONNATHAPUACHUTAMURTHY  
SUPERVISORY PATENT EXAMINER  
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